PRESENTED BY CAL PIERSON, PRESIDENT

MHA
Maryland
Hospital
Association

MHA CERTIFICATE OF NEED (CON) WORK GROUP COMMENTS TO MHCC CERTIFICATE OF NEED TASK FORCE

June 7, 2005

Introduction

The Maryland Hospital Association (MHA), on behalf of its 69 acute and specialty care member institutions, is pleased to submit comments to the Maryland Health Care Commission (MHCC, or the commission) Certificate of Need (CON) Task Force on ways to improve the CON process in Maryland. These comments are submitted without waiving the right of our members to independently comment.

Over the years, Maryland hospitals have supported an effective and rational CON process. Periodic comprehensive reviews such as this one help keep the process effective. MHA endorses the existing CON program but believes strongly that it needs to incorporate changes to streamline, facilitate, and enhance the process. Our comments focus primarily on the process of the CON review and areas where we think improvements can be made.

As the health care environment evolves, communities change, and medical technology reaches new levels, the CON program will continue to have a role in determining how health care is delivered in Maryland. Like in other parts of the country, the physical plants of Maryland hospitals are aging and in need of modernization. At the same time, hospitals are being pressed to expand their facilities to meet the growing health care needs of their communities. New technologies and improved processes in clinical care information management have created opportunities to improve the quality of care and patient safety, as well as make the delivery of health care more efficient and effective.

The creation of this task force is timely and will provide an opportunity to learn from our past experiences and to consider new ideas and approaches for the future.

MHA Process

In January 2005, MHA convened a work group of hospital representatives and subject matter experts to review the CON process and identify areas for improvement. As part of their work, they surveyed all MHA members for their concerns, reviewed the State Health Plan (SHP), and analyzed their historical experiences with the CON process. A list of work group members can be found in Appendix 1.

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Summary of MHA Recommendations

State Health Plan (SHP)

- ***Update The State Health Plan (SHP) And Keep It Current***
  Many of the current system standards are obsolete and/or redundant and should be repealed. Others, such as The American Institute of Architects (AIA) guidelines for square footage, should be adopted.

- ***Eliminate The Use Of Standards Not "Formally" Adopted in the SHP***
  Only standards promulgated and detailed in the SHP should be used in the CON review process.

- ***Align Acute Care Bed Need Projections With The Licensure Law***
  The CON and bed need regulations should be changed to use a 71.5 percent occupancy rate, instead of the current 80 percent occupancy rate, to reflect the statutory standard for licensed beds of 140 percent of average daily census.

- ***Better Define Total Available Physical Capacity and Bed Space***
  The definition of physical capacity needs to take into account modern architectural and patient care standards and public policy concerns such as the need for adequate surge capacity.

CON Process

- ***Restore The Original Spirit Of The Completeness Reviews***
  Completeness reviews should only address whether necessary application components are technically complete.

- ***Be Judicious And Time-Sensitive In Asking Relevant Additional Questions***
  All questions from commission staff or reviewers should be relevant and posed within 45 days of docketing.

- ***Streamline Standards Review And Documentation***
  Adopt a "checklist" approach for documenting compliance with standards and focus limited MHCC staff resources on areas where the more complex compliance problems might exist.

- ***Encourage Efficient Use of Resources By Allowing Shell Space***
  MHCC should allow hospitals to construct shell space under certain circumstances and within certain parameters to support the efficient use of health care dollars.

- ***Create A "Fast Track" Review Process***
  An abbreviated review process should be created for certain types of projects, such as those that do not include new beds and/or services. For these "fast track" projects, staff reports should be issued within 60 days and a commission decision should be rendered in 90 days or the project is deemed "approved."

- ***Eliminate Unnecessary Redocketing***
  After an application has been submitted, redocketing should not be required for changes due to requests made by commission staff or reviewers, changes made to the SHP, or changes in the MHCC's bed need projections.

Coverage

- ***Raise The Capital Threshold To At Least $7.5 Million***
  The capital threshold should be raised to at least $7.5 million, adjusted annually for inflation, to better reflect the increasing costs of capital improvement projects, as well as the increasing need for physical plant upgrades.

- ***Expand The CON Business Office Equipment Exemption To Include Health Information Technology/Medical Information Systems***
  Enhancements in health information technology/medical information systems improve the efficiency, effectiveness, and quality of care at a hospital, but do not necessarily relate specifically to the development of a new service. They should be considered as business or office equipment, and, therefore, legally exempted from the CON process.

The remainder of these comments outlines our work group's rationale and concerns for the recommendations in each of the identified areas for improvement.

State Health Plan

Update The State Health Plan (SHP) And Keep it Current

A solid CON process depends in large part on the quality of the review standards that are used. It has been almost ten years since the current SHP for acute care services has been updated with regard to review, criteria, and standards for the CON process. Given the rapid changes in the health care environment, a periodic update of the SHP section on acute care services is an essential part of improving the current CON process. The current SHP standards should be reviewed with the goal of eliminating those standards that are outdated, redundant, no longer apply to current practices, or have become current practices. Once formally adopted, the standards need to be kept current and maintained.

During our study, MHA quickly found that most of the standards for acute care services were outdated. Many of them no longer apply to current hospital construction, renovations, or operations. Many of them also address areas where change was needed historically but is no longer needed today because practices have evolved.

Table 1, attached, identifies the standards that MHA believes should be eliminated and why.

One specific area of comment relates to the current standards in the SHP for hospital construction square footage. Our work group felt strongly that these are antiquated and in need of updating. The MHCC should adopt the American Institute of Architects (AIA) guidelines for square footage as it applies to hospital construction. These are widely used and generally accepted guidelines that are updated on a regular basis. Adoption of these guidelines would work similarly to the way the commission currently uses the Marshall and Swift Valuation Quarterly. Further, since medical facilities are proposing construction for future use, the SHP needs to be flexible enough to allow applicants to demonstrate how their projects meet proposed AIA recommendations. Projects in the queue for CON consideration may be designed by architects using proposed 2006 AIA guidelines to ensure that a facility is as up-to-date as possible.

Eliminate The Use Of Standards Not "Formally" Adopted In The SHP

One of the longstanding tenets of the planning and CON process in Maryland is that criteria and standards against which an application will be measured are detailed in the SHP. The SHP includes general goals and objectives, as well as specific standards for different services. Prior to adoption, these criteria and standards are proposed for incorporation into the SHP and an opportunity is afforded for public comment and review. Through this process, interested parties are able to suggest amendments or changes to the proposed criteria and standards before they become regulation. The promulgation of standards in the SHP provides the opportunity in advance for all

interested applicants and others to see the standards being used to review their CON application.

Unfortunately, the planning and CON process has strayed from the accepted practice of using criteria and standards formally promulgated and adopted in the SHP. Applicants are subject to standards that are not in the SHP and are not available to them in advance as they plan their projects and prepare CON applications. The commission should make service-specific decisions based upon objective standards formally adopted through the regulatory process, rather than applying *ad hoc* standards.

Concerns include the use of *ad hoc* criteria relating to square footage and bays for emergency room expansions and the use of *ad hoc* requirements for patient safety. For instance, CON applications for expansions and renovations of hospital emergency rooms are measured against design standards contained in the American College of Emergency Physicians Guide to Emergency Room Design. These standards are not formally part of the SHP.

With regard to patient safety, hospitals are very supportive of efforts to advance patient safety initiatives in our facilities. However, reviewers seem to be relying on evolving *ad hoc* standards, developing one *ad hoc* standard in the process of reviewing one hospital's CON application and then applying it again in reviewing the CON application for another project with similar characteristics. When it is applied a second time, the *ad hoc* standard evolves again, making it difficult for hospitals planning projects to anticipate what standard will be used to judge them. Any standard used in a regulatory process for CON reviews should be promulgated in advance and become part of SHP review criteria.

Align Acute Care Bed Need Projections With The Licensure Law

Currently, the commission requires applicants to complete the statistical projections in Table 1 of the CON application based on a medical-surgical occupancy of approximately 80 percent. As medical-surgical beds comprise the majority of hospital beds, this effectively means that the facility's overall occupancy is targeted at approximately 80 percent. This is inconsistent with the statutory licensure law which established the 140 percent rule that calculates licensed bed capacity based on 140 percent of the average daily census (ADC) which is equivalent to an occupancy rate of about 71.5 percent. When the official hospital licensure number is calculated each year, it is based on the 140 percent rule or a 71.5 percent occupancy rate, not the 80 percent currently used by the commission.

The bed need projections should be changed to a 71.5 occupancy rate to be consistent with the licensure law.

Better Define Total Available Physical Capacity and Bed Space

When a hospital submits a CON for renovation of existing patient care areas along with the construction of new beds, there is often confusion and debate about what constitutes legitimate bed space. "Bed space" needs to be defined in a way that focuses on physical capacity as opposed to licensed capacity.

Currently, old patient care areas that look like patient care rooms (e.g., they may still have oxygen and gas lines in the wall) are considered bed space by the MHCC staff and have to be reconfigured if they are not to be counted as available capacity. Counting these as available capacity forces the hospital to deduct these spaces that cannot be used properly for patient care from any new bed space that is being requested.

Moreover, the counting of "headwalls" with the fear that areas converted to private rooms would be converted back to semi-private rooms holds little validity. JCAHO and the American Institute of Architects (AIA) both comment extensively on this issue, making the argument that having private rooms can be an important element in improving patient safety by reducing the risk of nosocomial infection and by providing greater flexibility in operations. Further, no hospital would reconvert a room that is too small by contemporary standards into a semi-private room, except in extreme circumstances, such as a community emergency or disaster. Also, old rooms that have been converted to other uses would not be desirable as modern patient rooms. These rooms simply do not hold up to contemporary architectural standards for patient care.

However, these older areas should not be discounted entirely and could be used for "overflow" or "surge" capacity to benefit the community at large. Since September 11, 2001, DHMH, MHCC, hospitals, and numerous sister agencies to MHCC have been looking at ways to create surge capacity. Surge capacity in both inpatient and outpatient settings is needed in the event of a disaster and/or when licensed beds are full. If a hospital applies for a CON and proposes to keep an existing unit for surge capacity as part of its project, MHCC should not require the hospital to reconfigure the space or deduct the beds but should approve the request, possibly asking the hospital for guarantees on when and under what circumstances the space will be used.

CON Process

Restore The Original Spirit Of The Completeness Review

Commission staff currently make little or no distinction between questions related to "completeness" and those having to do with "additional information." COMAR 10.24.01.08C(2) states: *The staff's review shall be to determine whether the application contains all the information required by the application form and that the certification is properly signed. If additional information is requested to ensure that the application is*

complete, staff shall specify in writing the information requested, which shall be submitted within 10 working days. Additional information may be requested by the staff beyond that which is required to make the application complete, which shall also be subject to a time limit for responding.

For a number of years, the commission has gone well beyond the spirit of the regulations and asked for substantive, additional information as part of its completeness review. This lengthens the review process inappropriately.

Completeness questions should only address whether a particular component of the application was not completed. Completeness review should not include an evaluation of the applicant's response to these components of the application. Docketing should occur once completeness is established and should not be held up for requests for additional information. We urge that the original spirit of the completeness review be restored so that it addresses only whether the necessary application components are complete.

Be Judicious And Time Sensitive In Asking Relevant Additional Questions

As mentioned previously with regard to patient safety, over the past several years, the CON process has been utilized more and more for research purposes through the application of *ad hoc* standards rather than the SHP process. Not only is this inappropriate, it also prolongs the time needed to complete a CON review.

"Additional information" questions are asked throughout the review process with little consideration of the relative importance or priority of the question or the regulatory time frame. For example, applicants have received additional information questions late in the review process regarding how electrical substations were set up and whether sprinkler systems were wet or dry. These types of questions should be explored in the context of promulgating standards in the SHP.

All questions from commission staff or reviewers should be asked within 45 days of docketing and focused on matters that are both relevant and important to whether CON approval may be granted. Applicants, of course, can provide additional information if they wish.

Streamline Standards Review And Documentation

The time and burden required for CON applications from both applicants and the commission's perspective would be greatly reduced if the amount of analysis necessary to document and demonstrate compliance to a given CON standard were more reasonable and proportional to the given standard. For standards that are straightforward in terms of their application and measurement, it should suffice to simply indicate that the applicant "complies with the standard." From a review of staff reports, it appears that this has not

been the case and that even simple standards often generate extensive analysis, detail, and verbiage.

Much time and effort could be saved by using more of a "checklist" approach to indicate a hospital's compliance with applicable standards. Discussion and staff analysis could then be focused and directed to the more complex and problematic areas.

Encourage Efficient Use of Resources By Allowing Shell Space

Currently, the MHCC does not routinely approve the construction of shell space for future use by hospitals. "Shell space" means newly constructed or existing vacated hospital space intended to be used at a later date when needed. Having shell space available gives hospitals a more cost-efficient alterative to starting a needed future expansion from scratch.

MHCC should allow hospitals to construct shell space under certain circumstances and within certain parameters to support the efficient use of health care dollars. Hospitals, in turn, should provide information about when and how they intend use the space. If needed, hospitals should also seek future CON approval for capital expenditures needed to convert the shell space over to its intended use.

A hospital should be allowed to build shell space as part of a new construction or expansion project if the hospital demonstrates that building the shell space is more cost efficient than constructing that space some time in the future.

Create A "Fast Track" Review Process

One of the ways to reduce the time and effort required to process a CON application and reduce the burden on both the applicants and MHCC staff is to establish a "fast-track" process for less complex applications that would require less analysis and review. For example, a hospital renovation project that includes no new services and no opposition from interested parties could be "fast-tracked." On the other hand, projects that request new services or involve opposition from interested parties may require more thorough analysis and a longer review process.

In addition to recommending these types of projects for a "fast track", we also recommend that staff reports on these projects be issued within 60 days of docketing and that a final commission decision be rendered within 90 days. If the staff report is not issued in 60 days or a final decision is not issued in 90 days, the project should be deemed "approved."

Table 2, attached, identifies the types of projects that should be subject to a "fast track," or abbreviated review process. It is not an exclusive list.

Eliminate Unnecessary Redocketing

Currently, if a hospital modifies its application in the course of the CON review for any reason, it must start the review over. COMAR 10.24.01.08E(3) states: *If an application is modified pursuant to §E(2) or (4) of this regulation, the applicant or applicants in the review shall have waived their right to a final decision by the commission within the statutorily prescribed time, and the application or applications shall be docketed again to permit public notice of and response to the modifications, as set forth in §F of this regulation.*

Often, a hospital will need to modify its application for reasons beyond its control, such as when the commission or a commission reviewer requests a change. These situations are different than when the hospital makes substantive changes to its application because the fundamental nature of its project has changed. These modifications should not require the hospital to begin the process again, which needlessly prolongs the time taken to review a process.
To facilitate the process and prevent undue delays, the process should be changed to allow commission staff requests but not have these requests result in redocketing. The regulations should be amended to eliminate the need for redocketing due to:

1. Requests made by commission staff or commission reviewers;

2. Changes made to the SHP during the application process; or,

3. Changes made in regulation to bed need during the application process.

Coverage

Raise the Capital Expenditure Threshold to at Least $7.5 Million

Maryland law requires the commission to adjust the statutory capital expenditure review threshold on an annual basis according to the Consumer Price Index-Urban (CPI-U) for the Baltimore Metropolitan Area.

The threshold has not been raised since the mid 1980's while the cost and need for construction have significantly increased. Raising the threshold to at least $7.5 million would relieve the MHCC of the administrative burden of reviewing these minor projects and allow hospitals to pursue them more quickly.

Expand The CON Business Office Equipment Exemption To Include Health Information Technology/Medical Information Systems

Currently, Maryland law states that a CON is not necessary before a health care facility makes a capital expenditure for business or office equipment that is not related to patient care.

With more hospitals making information technology investments, the line between projects that are directly related or not directly related to patient care blurs. Projects to modernize existing IT services also serve to enhance patient care and promote patient safety. Such expenditures are typically not related to the development of new services, but are meant to improve the efficiency, effectiveness, and quality of health care delivery. MHA recommends that the current CON exemption for business office equipment be expanded to include health information technology and/or medical information systems.

Conclusion

MHA commends the MHCC for undertaking this effort to modernize the CON process. We hope that our recommendations will help to facilitate the work of the task force. We believe that the process can be made much more efficient without losing its regulatory focus.

APPENDIX 1

MHA Certificate of Need Work Group Membership

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TABLE 1

System Standards Proposed For Changes Or Deletions

Standard	Reason for Change
.06A(2) Utilization Review Control Programs	This standard is unnecessary since all hospitals must have a UR program.
.06A(3) Travel Time	The standard is being met in every jurisdiction.
.06A(4) Information Regarding Charges	Every hospital currently meets this standard.
.06A(5) Charity Care Policy	Hospitals all have charity care policies.
.06A(6) Compliance with Quality Standards	Every hospital is accredited by JCAHO, though are not required to do so.
.06A(7) Transfer and Referral Agreements	This standard should be deleted unless it can be demonstrated that there are specific problems today with transfers.
.06A(8) Outpatient Services	Every hospital meets the standard in different ways.
.06A(9) Interpreters	All hospitals provide interpreter services.
.06A(10) In-Service Education	All hospitals comply.
.06A(11) Overnight Accommodations	All hospitals comply.
.06A(12) Required Social Services	All hospitals comply.
.06A(19) Minimum Size for Pediatric Unit	This standard should be eliminated. Pediatric admissions have declined. Ten beds may be too many to require.
.06A(20) Admission to Non-Pediatric Beds	This standard should be eliminated. Pediatric admissions have declined.
.06A(21) Required Services When Providing Critical Care	This standard should be eliminated. Every hospital has, at least, referral relationships for these services.
.06A(22) Average Length of Stay for Critical Care Units	All hospitals have financial incentives to reduce length of stay as appropriate.
.06A(23) Waiver of Standards for Proposals Responding to the Needs of AIDS Patients	This standard is probably obsolete and should be eliminated.
.06B(1) Compliance with Systems Standards	This standard is redundant.
.06B(2) Duplication of Services and Adverse Impact	Since there are other standards that address (a), (a) should be eliminated.
.06B(4) Burden of Proof Regarding Need	This standard is redundant.
.06B(5) Discussion with Other Providers	This standard is ineffective and should be eliminated.
.06B(9) Maximum Square Footage	This standard should cite the AIA guidelines.
.06C(2) Compliance with System Standards	This standard is redundant.
.06C(3) Conditions for Approval	This standard is redundant.
.06C(5) Maximum Square Footage–Renovations	This standard should say that the standard for new construction is applicable.

TABLE 2

Potential Projects Eligible for Abbreviated Reviews

Project Type	Applicable Standard	Staff Report	MHCC Decision
Renovation Projects-no new beds.	C(4), C(6)-C(9)	60 days	90 days
New Construction-no new beds or services	B(7), B(10)-B(12)	60 days	90 days
Renovation or New Construction Projects-new beds at or below the minimum of the commission's bed need projections	A(1), B(7), B(10)-B(12), C(4), C(6)-C(9)	60 days	90 days
Health information technology and medical information systems	The business office equipment exemption should be expanded to include these projects. But, at a minimum, they should be eligible for an abbreviated review	60 days	90 days